

REMARKS

The Examiner issued a restriction requirement on September 24, 2003 alleging that the present application claims a potentially **infinite** number of distinct **inventions**. Specifically, the Examiner has divided the application into the following seven groups:

- Group I: Claims 1-13, 22-24 and 37-46, are drawn to a recombinant adenovirus carrying an HIV envelope antigen and an immunostimulatory sequence;
- Group II: Claims 1, 25-36 and 37-46, drawn to a recombinant adenovirus carrying a HIV gag gene product, a protease of HIV and an immunostimulatory Sequence;
- Group III: Claims 47-57, 61-66 and 86, drawn to a recombinant adenovirus carrying a first HIV antigens under control of a first promoter and second HIV antigen under the control of a second promoter;
- Group IV: Claims 47, 57-66 and 86, drawn to a recombinant adenovirus carrying a first HIV antigens under control of a first promoter and second HIV antigen under the control of a second promoter, wherein antigens are selected from multiple V3 loops of different glades;
- Group V: Claims 47, and 67-86, drawn to a recombinant adenovirus carrying two Gag gene products of HIV;
- Group VI: Claims 87-91, drawn to a method for enhancing the immunity of host to HIV infection by using a recombinant adenovirus plus an immunostimulatory cytokine; and
- Group VII: Claims 92-93, drawn to a method for enhancing the immunity of host to HIV infection by using a recombinant adenovirus.

Within each of Groups I-V, the Examiner further restricts it into multiple distinct **inventions** as to the type or sequence of the "HIV antigen" recited in the respective independent claims.

For example, within Group III (claims 47-57, 61-66, and 86), the Examiner further restricts the claims into multiple inventions for the following 3 categories of HIV antigens: 1) HIV envelop proteins; 2) HIV envelop proteins with specific sequences; and 3) HIV regulatory protein. For proteins within each category, the Examiner specifically states that “this is **not the species election** because each single protein having different structures that required different search and exhibit different patentable weights” (emphasis added). Applicants disagree with the Examiner’s restriction requirement.

Pursuant to 37 C.F.R. §1.143, Applicants provisionally elect Group III and respectfully request the Examiner’s modification of the restriction requirement as to the particular HIV antigens specified in dependent claims within Group III.

Independent claim 47 as amended specifies a recombinant adenovirus carrying a first HIV antigen under control of a first promoter and a second HIV antigen under the control of a second promoter, expression of the first and second HIV sequences eliciting an immune response directed against the first and second HIV antigens upon infection of the host by the recombinant virus.

Applicants submit that the term “HIV antigen” recited in independent claim 47 is a generic term and claim 47 is a **generic claim**. The particular types or sequences of HIV antigens recited in the dependent claims are patentably distinct **species** within the genus of “HIV antigen”. These species are specific, different embodiments of the generic claim. Pursuant to MPEP 806.04(c), the “fact that a genus for two different embodiments is capable of being conceived and defined, does not affect the independence of the embodiments”, even for a case that “contains no disclosure of any commonality of operation, function or effect”. Although the specific types or sequences of the HIV antigen have different structures, they share a common genetic character of being encoded by the HIV genome and being polypeptide components of the HIV virion. These HIV antigens are patentably distinct species of the genus “HIV antigen”.

The Examiner also required Applicants to elect several patentably distinct species of the claimed invention.

Accordingly, Applicants elect the following species:

1) for a promoter: CMV promoter (claim 85);

2) for a cytokine: IL-2 (claim 82);

3) for HIV clade: HIV clade A (claim 59); and

4) for HIV strain: BH10.

Accordingly, claims 1-46 and 87-93 are canceled without prejudice. New claims 94-97 are added. Support for these new claims appears, for example, in claims 31-36 as originally filed; and in Figure 55B.

Applicants reserve the right pursuant to 37 C.F.R. §1.141 to pursue claims to the non-elected species or subgenus in this application in the event that a generic claim is found to be allowable. Applicants also reserve the right pursuant to 35 U.S.C. §121 to file one or more divisional applications directed to the non-elected species or subgenus during the pendency of the present application.


CONCLUSION

Applicants earnestly believe that the application is in condition for allowance and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 22488-712).

Respectfully submitted,

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